

# MLS Laboratory Update: Possible performance issues with BioFire FilmArray Gastrointestinal (GI) panel for *Cryptosporidium spp.*

JUNE 14, 2022

## Purpose of this Message:

To ask for assistance and to notify MLS laboratories that MDH-PHL and other state public health labs have observed possible test performance issues with the BioFire FilmArray gastrointestinal (GI) panel (BioMerieux, France) for *Cryptosporidium spp.* that may indicate an increase in false positive test results in the last 6 months. To identify possible causes, BioMerieux has requested assistance in collecting data on specimens in question.

## Action Item:

Please be prepared to provide information to BioMerieux about specimens that may have had a possible false positive result for *Cryptosporidium spp.* by the BioFire FilmArray GI Panel. See details below.

## Laboratory Action Requested:

1. The MDH staff may be contacting clinical labs after receipt of specimens to MDH-PHL.
2. If contacted, please provide information regarding performance issues with the *Cryptosporidium* target on the BioFire FilmArray gastrointestinal (GI) panel to the BioFire Support Center either by phone 1-801-736-6354 or by email to [support@biofiredx.com](mailto:support@biofiredx.com) and copy [cryptonet@cdc.gov](mailto:cryptonet@cdc.gov).
3. Use the Excel spreadsheet that MDH will send to you to provide information to BioMerieux and CryptoNet directly. You are requested to provide the following information:
  - a. Patient age and gender
  - b. Any possible harmful incidences to the patient due to BioFire results (e.g., delayed treatment, prolonged hospital stay)
  - c. Patient's clinical symptoms
  - d. Patient's final diagnosis
  - e. BioFire run files
  - f. Pouch lot and instrument serial number
  - g. Decontamination procedure and frequency
  - h. Sample type and collection date
  - i. Cary Blair lot number, manufacturer, expiration date

## Background:

- State and federal partners of the CDC-hosted Cryptosporidium network, CryptoNet (<https://www.cdc.gov/parasites/crypto/cryptonet.html>), have observed possible test performance issues with the BioFire FilmArray gastrointestinal (GI) panel for *Cryptosporidium spp.* To date, five CryptoNet sites, including MDH-PHL, have reported potential discrepancies that indicate false positive *Cryptosporidium* results from the FilmArray.
- Currently, MDH-PHL performs nested PCR targeting 18S and GP60 genes, real time PCR and DFA (direct fluorescent antibody) to identify and characterize *Cryptosporidium* species for surveillance purposes.

## Additional Information:

**Questions:** Please contact Jisun Haan, Ph.D, Interim Enterics unit supervisor ([jisun.haan@state.mn.us](mailto:jisun.haan@state.mn.us) 651-201-5041)

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